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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/235,153 01/22/99 GEORGES

F SB-B750

EXAMINER

HM22/0710

LORUSSO & LOUD
3137 MOUNT VERNON AVENUE
ALEXANDRIA VA 22305

ETNSMANN, T	
ART UNIT	PAPER NUMBER

1655
DATE MAILED:

14

07/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/235,153	GEORGES ET AL.	
	Examiner	Art Unit	
	Juliet C. Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 May 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 17 and 19-26 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 15, 16, 18 and 27-33 is/are rejected.
- 7) Claim(s) 10 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
- 18) Interview Summary (PTO-413) Paper No(s). _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5-9, 16, 18, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Murata (EP 0818138 A1).

Murata teaches a method of making a genetically transformed plant comprising: (a) introducing into a plant cell capable of being transformed and regenerated into a whole plant a DNA expression cassette comprising, in addition to DNA sequences required for transformation and selection in plant cells, a DNA sequence that, under the control of a promoter active in plant cells, encodes a heterologous enzyme capable of modifying the utilization of the substrate choline in the anti-nutritional phenylpropanoid pathway, and (b) recovering a plant which has an altered content of at least one product of the secondary metabolic pathway (see Examples 8 (page 8) and 14 (page 10)). Murata further grows the plant obtained under conditions which permit the formation of a seed (page 10, line 10, for example). Murata teaches the plants and seeds produced by the plants obtained by this method (page 10, line 10-15), these seeds

inherently have reduced lignin and sinapine content. Murata exemplifies the use of this method to produce transgenic *Arabidopsis thaliana*, of the family cruciferae, (example 8) and rice, *Oryza sativa*- family gramineacae (example 10).

4. Claims 1-6 and 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Ooijen (US 5543576).

Van Ooijen et al. teach a method of making a genetically transformed plant comprising:
(a) introducing into a plant cell capable of being transformed and regenerated into a whole plant a DNA expression cassette comprising, in addition to DNA sequences required for transformation and selection in plant cells, a DNA sequence that, under the control of a promoter active in plant cells, encodes phytase, which is a heterologous enzyme capable of modifying the utilization of the substrate anti-nutritional factor phytate, and (b) recovering a plant which has an altered content of at least one product of the secondary metabolic pathway (see Examples 8-11 Col. 16-17, and Examples 18-19, Col. 22-24).

Van Ooijen et al. teach growing the plant obtained under conditions which permit the formation of a seed, and teach teaches the plants and seeds produced by the plants obtained by this method (Col. 23, lines 66-67, for example). Van Ooijen et al. teach that many plant species are useful in this method, including monocots such as *Orza sativa* (of the family Gramineae) and dicots such as *Brassica napus* (Col. 6, lines 11-18). Van Ooijen et al. specifically teach the use of the plant products produced as animal feed (Col. 17, lines 35-53).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3, 4, 15, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murata in view of Willmitzer *et al.* (WO 92/01042).

Murata teaches a method of making a genetically transformed plant comprising: (a) introducing into a plant cell capable of being transformed and regenerated into a whole plant a DNA expression cassette comprising, in addition to DNA sequences required for transformation and selection in plant cells, a DNA sequence that, under the control of a promoter active in plant cells, encodes a heterologous enzyme capable of modifying the utilization of the substrate choline in the anti-nutritional phenylpropanoid pathway, and (b) recovering a plant which has an altered content of at least one product of the secondary metabolic pathway (see Examples 8 (page 8) and 14 (page 10)). Murata further grows the plant obtained under conditions which permit the formation of a seed (page 10, line 10, for example). Murata teaches the plants and

seeds produced by the plants obtained by this method (page 10, line 10-15), these seeds inherently have reduced lignin and sinapine content. Murata exemplifies the use of this method to produce transgenic *Arabidopsis thaliana*, of the family cruciferae, (example 8) and rice, *Oryza sativa*- family gramineaceae (example 10). Murata further teaches that choline oxidase is an enzyme which is commercially available (p. 2, lines 55-56).

Murata does not teach methods in which the promoter is tissue selective, or specifically seed selective.

Willmitzer *et al.* teach transgenic plants expressing industrial enzymes, and methods for the production of such plants. The industrial enzymes suggested by Willmitzer *et al.* for use in these methods include oxidoreductases (p. 6, line 22). They teach that the DNA sequence encoding the enzyme of interest under the control of a promoter such as a seed specific promoter such as the phaseolin promoter (p. 4, lines 27-31). Willmitzer *et al.* teach a variety of plants useful for the introduction of the enzyme, including tobacco, potato, tomato, pea, soy, and cereals (p. 7, lines 19-21), and further teach that either the entire plant or parts thereof may be useful for animal feeds (p. 7, lines 10-13). Willmitzer *et al.* teach vectors for the integration of foreign DNA into plant cells and the introduction of these vectors into *Agrobacterium* species (p. 9, line 28-p. 9, line 19).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used seed specific promoters for the expression of choline oxidase in plants as taught by Willmitzer *et al.* The ordinary practitioner would have been motivated to do so by the fact that choline oxidase is an enzyme which is sold commercially and because Willmitzer *et al.* expressly teach that the production of enzymes in plants overcomes two major

obstacles in industrial enzyme production, "Firstly, higher plants have biosynthetic capacity to perform the requisite post-translational modifications occurring in eukaryotic cells of mammalian or other origin. Secondly, transgenic plants grown in the field need very little extra energy for growth (and hence for the production of proteins such as industrial enzymes) and furthermore do not give rise to any major problems with respect to waste management (p. 4, lines 10-18)." Furthermore, Murata provides the nucleic acid sequence encoding choline oxidase and demonstrates that it can be successfully expressed in transgenic plants. Willmitzer *et al.* provide the necessary suggestion and direction to motivate the production of choline oxidases in plants, and thus, in the absence secondary considerations such as unexpected results, the claimed invention is obvious over the prior art.

Allowable Subject Matter

8. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. While the prior art teaches methods for producing transgenic plants expressing heterologous choline oxidase (Murata, for example) and different transgenic plants expressing betaine aldehyde dehydrogenase (Holmström *et al.*, for example), the prior art does not teach or suggest methods in which both choline oxidase and betaine aldehyde dehydrogenase are introduced into the same plant under the control of a seed specific promoter.

Conclusion

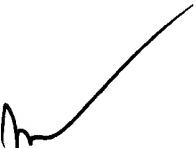
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Austin-Phillips *et al.* teach that phytate is generally considered an anti-nutritional

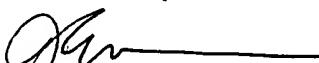
factor due to its ability to chelate multivalent cations such as calcium and iron thus forming insoluble complexes.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


**JEFFREY FREEDMAN
PRIMARY EXAMINER**


**Juliet C. Einsmann
Examiner
Art Unit 1655**

June 29, 2001